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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>ZKI79P3848</b>	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/PL03/00019</b>	International filing date ( <i>day/month/year</i> ) <b>05/03/2003</b>	Priority date ( <i>day/month/year</i> ) <b>06/03/2002</b>
International Patent Classification (IPC) or national classification and IPC <b>A61B5/15</b>		
Applicant <b>"HTL STREFA" SP. Z O.O. et al.</b>		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 14 sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I   <input checked="" type="checkbox"/> Basis of the report II   <input type="checkbox"/> Priority III   <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV   <input type="checkbox"/> Lack of unity of invention V   <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI   <input type="checkbox"/> Certain documents cited VII   <input type="checkbox"/> Certain defects in the International application VIII   <input type="checkbox"/> Certain observations on the international application</p>		

Date of submission of the demand <b>24/09/2003</b>	Date of completion of this report <b>02.02.2004</b>
Name and mailing address of the International preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer <b>Rick, K</b> Telephone No. +49 89 2399 7246



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/PL03/00019

**I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):  
**Description, pages:**

1-9	as received on	03/01/2004 with letter of	23/12/2003
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**Claims, No.:**

1-4	as received on	03/01/2004 with letter of	23/12/2003
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**Drawings, sheets:**

1/4-4/4	as received on	03/01/2004 with letter of	23/12/2003
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2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description,      pages:      10
- the claims,      Nos.:      5-8

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the drawings, sheets: 5/9-9/9

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):  
*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:  
 the entire international application.  
 claims Nos. 3,4.

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):  
 the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):  
 the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.  
 no international search report has been established for the said claims Nos. 3,4.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- the written form has not been furnished or does not comply with the standard.  
 the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N) Yes: Claims 1,2

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	No:	Claims
Inventive step (IS)	Yes:	Claims 1,2
	No:	Claims
Industrial applicability (IA)	Yes:	Claims 1,2
	No:	Claims

2. Citations and explanations  
see separate sheet

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 3 and 4 are identical with claims 7 and 8 as originally filed. Following an objection of lack of unity of invention by the International Searching Authority (see Article 17 (3)(a) PCT), no search report had been established for present claims 3 and 4 (former claims 7 and 8). Accordingly examination can not be carried out for the subject-matter of present claims 3 and 4. However, in case the application proceeds into the regional phase before the EPO, the applicant is reminded that a search for claims 3 and 4 may be carried out during examination before the EPO in accordance with Rule 112 EPC.

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The document EP-A-1 142 534 (D1) of the international search report, as acknowledged by the applicant and considered to represent the most relevant state of the art, discloses a device for puncturing patient's skin comprising a sleeve, a push element, a piston and an indicating-adjusting member with at least one indicator of the pre-set puncturing depth as defined in present claim 1.
2. The subject-matter of claim 1 differs from D1 in that said indicator is located in a circumferential groove in the lower part of the sleeve with external cut-outs.
3. The above feature solves the problem to indicate the adjusted penetration depth of the puncturing device simultaneously with the stepwise change of the adjusting member in an easy readable manner.
4. All further documents of the international search report are less relevant for the subject-matter of present claim 1. Accordingly the combination of features of claim 1 is neither known, nor rendered obvious by, the available prior art and meets the requirements of Article 33(2)-(4) PCT.

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5. Claim 2 dependent thereon defines a further advantageous embodiment and as such also meets the requirements of Article 33 PCT.